ART 34 AMOT

## **CLAIMS**

- A diagnostic method for detecting infection with an avian influenza virus of a specific epidemic strain
   (HxNy) comprising the steps of:
  - providing a recombinant antigen comprising an amino acid sequence of a neuraminidase protein (NAy) or a fragment thereof;
- 10 contacting said antigen with a specimen of biological fluid from an animal to be tested; and
  - determining whether the antigen has any antineuraminidase antibodies bound thereto by means of a
    positivity detection test.

15

2. A diagnostic method according to Claim 1 wherein the antigen is encoded by a nucleotide sequence derived from the genome of an avian influenza virus with epidemic subtype (HxNy).

20

- 3. A diagnostic method according to Claim 1 or 2 wherein the antigen is obtainable by expression in insect cells using a baculovirus vector.
- 25 4. A diagnostic method according to any one of the preceding claims wherein the method is capable of

discriminating between infected animals and vaccinated animals.

- 5. A diagnostic method according to any one of the preceding claims wherein the specimen of biological fluid is from an animal which has been vaccinated against avian influenza.
- A diagnostic method according to any one of the 10 preceding claims wherein the detection test is carried out on specimens of biological fluid from a population of animals at least some of which have been subjected to vaccination by means of a heterologous vaccine characterized by the subtype same viral 15 haemagglutinin Hax and а different subtype neuraminidase Nay.
- 7. A diagnostic method according to any one of the Claims 1 to 6 in which said test for the detection of positivity is an immunofluorescence or immunoperoxidase test.
  - A diagnostic method according to any one of the Claims 1 to 6 in which said test for the detection of positivity is an ELISA test.

- 9. A diagnostic method according to any one of the Claims 1 to 6 in which said test for the detection of positivity is a colour test that is adapted to be carried out on the field by means of an inert support 5 with said antigen adsorbed on.
  - 10. A process for vaccinating animals against avian influenza virus infection with specific epidemic strain HxNy comprising the steps of:

10

- preparing a heterologous vaccine characterized by the same subtype of viral haemagglutinin Hax and a different subtype of neuraminidase Naz;
- administering said vaccine to at least one group
   of animals selected from a population at risk of infection; and
  - determining whether an animal is infected with the virus using a diagnostic method according to any one of Claims 1 to 9.

20

11. A vaccination process according to claim 10, in which said vaccine is a natural vaccine obtained by inactivating a natural virus.

ART 34 MINOS

- 12. A diagnostic kit for detecting infection with avian influenza virus with epidemic subtype (HxNy), comprising:
- 5 a solid support of an inert material;
  - a recombinant antigen comprising an amino acid sequence of a neuraminidase protein NAy or a fragment thereof in a state that is substantially non modified as compared with that of the specific avian influenza virus strain (HxNy), said antigen being associated onto said solid support; and
  - a reagent that is adapted to colorimetrically evidence the positivity to infection in the presence of anti-NAy antibodies contained in a biological fluid of an animal.
  - 13. A diagnostic kit according to Claim 12 wherein the kit is capable of discriminating between infected animals and vaccinated animals.

20

10

15

14. A diagnostic kit according to Claim 12 or 13, in which said support is selected from the group comprising: latex spheres, plastic supports.